

# PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	INSOMNIA AGENTS
BRAND NAME* (generic)	<p><b>AMBIEN</b> (zolpidem)</p> <p><b>AMBIEN CR</b> (zolpidem extended-release)</p> <p><b>(flurazepam)</b></p> <p><b>DORAL</b> (quazepam)</p> <p><b>(estazolam)</b></p> <p><b>HALCION</b> (triazolam)</p> <p><b>LUNESTA</b> (eszopiclone)</p> <p><b>RESTORIL</b> (temazepam)</p> <p><b>ROZEREM</b> (ramelteon)</p> <p><b>SONATA</b> (zaleplon)</p>
<p><b>Status: CVS Caremark Criteria</b>  <b>Type: Post Limit Prior Authorization</b></p>	

## POLICY

### FDA-APPROVED INDICATIONS

#### **Ambien**

Ambien is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Ambien has been shown to decrease sleep latency for up to 35 days in controlled clinical studies. The clinical trials performed in

support of efficacy were four to five weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.

### **Ambien CR**

Ambien CR is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset). The clinical trials performed in support of efficacy were up to three weeks (using polysomnography measurement up to two weeks in both adult and elderly patients) and 24 weeks (using patient-reported assessment in adult patients only) in duration.

### **Flurazepam**

Flurazepam hydrochloride capsules are indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.

Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

### **Doral**

Doral is indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. The effectiveness of Doral has been established in placebo-controlled clinical studies of five nights duration in acute and chronic insomnia. The sustained effectiveness of Doral has been established in chronic insomnia in a sleep lab (polysomnographic) study of 28 nights duration. Because insomnia is often transient and intermittent, the prolonged administration of Doral tablets is generally not necessary or recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered.

### **Estazolam**

Estazolam is indicated for the short-term management of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakenings. Both outpatient studies and a sleep laboratory study have shown that estazolam administered at bedtime improved sleep induction and sleep maintenance. Because insomnia is often transient and intermittent, the prolonged administration of estazolam is generally neither necessary nor recommended. Since insomnia may be a symptom of several other disorders, the possibility that the complaint may be related to a condition for which there is a more specific treatment should be considered. There is evidence to support the ability of estazolam to enhance the duration and quality of sleep for intervals up to 12 weeks.

### **Halcion**

Halcion is indicated for the short-term treatment of insomnia (generally 7 to 10 days). Use for more than two to three weeks requires complete re-evaluation of the patient. Prescriptions for Halcion should be written for short-term use (7 to 10 days) and it should not be prescribed in quantities exceeding a one-month supply.

### **Lunesta**

Lunesta is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, Lunesta administered at bedtime decreased sleep latency and improved sleep maintenance. The clinical trials performed in support of efficacy were up to six months in duration. The final formal assessments of sleep latency and maintenance were performed at four weeks in the six-week study (adults only), at the end of both two-week studies (elderly only) and at the end of the six-month study (adults only).

### **Restoril**

Restoril is indicated for the short-term treatment of insomnia (generally 7 to 10 days). For patients with short-term insomnia, instructions in the prescription should indicate that Restoril should be used for short periods of time (7 to 10 days). The clinical trials performed in support of efficacy were two weeks in duration with the final formal assessment of sleep latency performed at the end of treatment.

### **Rozerem**

Rozerem is indicated for the treatment of insomnia characterized by difficulty with sleep onset. The clinical trials performed in support of efficacy were up to six months in duration. The final formal assessments of sleep latency were performed after two days of treatment during the crossover study (elderly only), at five weeks in the six-week studies (adults and elderly), and at the end of the six-month study (adults and elderly).

### **Sonata**

Sonata is indicated for the short-term treatment of insomnia. Sonata has been shown to decrease the time to sleep onset for up to 30 days in controlled clinical studies. It has not been shown to increase total sleep time or decrease the number of awakenings. The clinical trials performed in support of efficacy ranged from a single night to five weeks in duration. The final formal assessments of sleep latency were performed at the end of treatment.

### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The drug is being prescribed for insomnia

**AND**

- Potential causes of sleep disturbances have been addressed (e.g., inappropriate sleep hygiene and sleep environment issues or treatable medical/psychological causes of chronic insomnia)

Quantity Limits apply.

### **POST LIMIT QUANTITY**

**Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.**

<b>Drug</b>	<b>1 Month Limit*</b>	<b>3 Month Limit*</b>
Ambien all strengths (zolpidem)	30 tablets/25 days	90 tablets/75 days
Ambien CR all strengths (zolpidem extended-release)	30 tablets/25 days	90 tablets/75 days
Lunesta all strengths (eszopiclone)	30 tablets/25 days	90 tablets/75 days
Rozerem all strengths (ramelteon)	30 tablets/25 days	90 tablets/75 days
Sonata all strengths (zaleplon)	60 capsules /25 days	180 capsules /75 days

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

### **REFERENCES**

1. Ambien [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; February 2019.
2. Ambien CR [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; February 2019.
3. Flurazepam [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; December 2018..
4. Doral [package insert]. Marietta, GA: Galt Pharmaceuticals LLC; August 2017.
5. Estazolam [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; December 2018.
6. Halcion [package insert]. New York, NY: Pharmacia and Upjohn Company; January 2019.

7. Lunesta [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; December 2018..
8. Restoril [package insert]. Webster Groves, MO: SpecGx LLC; February 2019.
9. Rozerem [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2018.
10. Sonata [package insert]. Bristol, TN: King Pharmaceuticals Inc.; December 2018.
11. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA.  
<http://www.micromedexsolutions.com/>. March 2019.
12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc.  
<http://online.lexi.com/>. Accessed March 2019.
13. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349.
14. Sateia MJ. International Classification of Sleep Disorders: highlights and modifications. *CHEST*. 2014; 146 (5): 1387-1394. doi: 10.1378/chest.14-0970
15. Qaseem A, Kansagara D, Forcica MA, Cooke M, Denberg TD, Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Epub, 2016. 165(2):125-33. doi: 10.7326/M15-2175. Epub 2016 May 3.
16. Morgenthaler T; Kramer M; Alessi C et al. Practice parameters for the psychological and behavioral treatment of insomnia: An update. An American Academy of Sleep Medicine report. *SLEEP* 2006; 29(11):1415-1419.
17. Schutte-Rodin S, Broch L, Buysse D, Dorsey C, Sateia M. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med* 2008; 4(5):487-504.